

Enzymatic Therapy

NATURAL MEDICINES®

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November 5, 2003

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

NOV 13 2003

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
EstroBalance™ with DIM	Hormone levels affect your body in many ways and can result in fatigue, mood swings, occasional PMS, menstrual cramps and difficulty losing weight.*	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

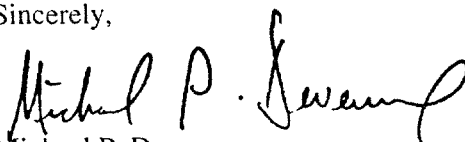
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/5/03

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer

EstroBalance™ with DIM 17e

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LET 13327

825 Challenger Drive
Green Bay, WI 54311-8328

Ph: 920-469-1313

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Enzymatic Therapy

NATURAL MEDICINES®

November 6, 2003

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740


RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
EstroBalance™ with DIM	With the Easy Answers Stage 1 you know you're getting; a solid nutritional foundation, supporting your bone health and balancing your hormone cycles naturally.*	Indolplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

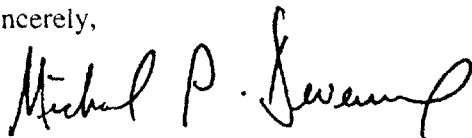
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/6/03

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux
Chief Financial Officer

EstroBalance™ with DIM 18e